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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,219	11/16/2006	David Helton	15513-1US	4859

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
02/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,219	HELTON ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 19-25* is/are pending in the application.

4a) Of the above claim(s) *10-16, 21, and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9 and 24* is/are rejected.

7)☒ Claim(s) *7,8,19,20 and 22-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/09, 06/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

This Office Action is in response to the amendment submitted on 10/20/09. Claims 1-16 and 19-25 are currently pending in the application, with claims 17-18 having being cancelled and claims 10-16, 21, and 25 having being withdrawn. Accordingly, claims 1-9, 19-20, and 22-24 are being examined on the merits herein.

Receipt of the aforementioned amended claims and IDS is acknowledged and has been entered.

Applicant's argument with respect to the objection of claims 1-9 and 19-20 has been fully considered. Given that applicant has amended the claims and corrected the informalities, such objection is now moot. Consequently, the objection of claims 1-9 and 19-20 is hereby withdrawn.

Applicant's argument with respect to the rejection of claim 6 under 35 U.S.C. §112, second paragraph has been fully considered. Given that applicant has amended the claims and corrected the informalities, such rejection is now moot. Consequently, the rejection of claim 6 under 35 U.S.C. §112, second paragraph is hereby withdrawn.

Applicant's argument with respect to the Obviousness Double Patenting (ODP) rejection of claims 1-5 and 9 has been fully considered. Given that co-pending

application 10/986, 485 is now abandoned, such rejection is now moot. Consequently, the ODP rejection of claims 1-5 and 9 is hereby withdrawn.

Applicant's traversal of the Obviousness Double Patenting (ODP) rejection of claims 1-5 and 9 over claims 1-9 and 12 of U.S. Patent 6,770,638 B2 is acknowledged, but since applicant did not put forth any arguments against this rejection, the ODP rejection is maintained for reasons of record as stated in the previous Office Action and restated below for applicant's convenience.

Applicant's argument with respect to the rejection of claims 1-6 and 9 under 35 U.S.C. §103(a) over Fick has been fully considered. Applicant argues that the addition of a methyl group to a compound having neurological properties is not an obvious substitution in view of the prior art research (i.e. Tecle) showing that the effect of such substitution is unpredictable and may in fact be deleterious. Such arguments are however not found persuasive as the Examiner contends that applicant's arguments and the prior art do not commensurate in scope with the claims. The Examiner respectfully points out that the compounds of the instant invention are directed to indolone compounds while Tecle et al. teach divergent compounds wherein the generic core structure is a pyridine. Consequently, the Examiner maintains that such structures are not structurally related or similar and thus no conclusion can be drawn about the addition of methyl groups to such compounds when compared to the instant invention. Moreover, Tecle et al. further suggest that the effect of the methyl group may be due to the steric bulk in the ring. Contrary to applicant's belief, no steric hindrance exist in the

instant invention since only 3 of the carbon atoms are occupied in formula III of the instant invention and Hydrogen due its size does not possess any steric bulkiness. Additionally, the Examiner refers applicant to M.P.E.P. 2144.0, which clearly states that a *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. As a result, an obviousness rejection based on similarity in chemical structure and function can entail the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (discussed in more detail below) and In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991). Thus, the Examiner maintains that in light of Fick et al. and applicant's own prior art, the instant compounds are indeed obvious and that substitution of a methyl group for hydrogen is an obvious modification absent unexpected or unobvious results. If applicant believes otherwise, it is incumbent upon applicant to demonstrate through side by side comparative data that substitution of a methyl group at R6 for a Hydrogen group leads to contrasting effectiveness of the neurological agents.

As for applicant's arguments regarding the withdrawal of the restriction requirement, such arguments are not found persuasive as the Examiner maintains that the instant claims are obvious and known in the prior art and therefore no special technical features exist among the different groups of the invention. As a result, a lack

of unity exists and restriction for examination purposes was indeed proper and is once again made FINAL.

For the foregoing reasons, the ODP rejection of claims 1-5 and 9 over co-pending application 10/986, 485; the objections and rejection of claim 6 are hereby withdrawn. The rejection of claims 1-6 and 9 under 35 U.S.C. 103(a) over Fick et al. remains proper. However, in view of applicant's amendment, the following modified ODP and 103 (a) Final rejections are being made.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 12 of U.S. Patent 6,770,638 B2 (hereinafter Fick US Patent Application No. '638). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a composition containing a compound of formula I further substituted by a formula III and a pharmaceutical carrier. The claimed invention and co-pending application Fick '638 are rendered obvious over another as the claimed invention teaches a subgenus of compounds with a alkyl group at the R6 position (i.e. the R6 of formula IIII) whereas Fick '638 teaches a subgenus of compounds containing a "hydrogen" at the same R6 position. Consequently, the Examiner contends that these compounds are obvious variants of one another and

therefore expected to behave similarly. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are *prima facie* obvious over the cited claims of U.S. Patent No. 6,770,638 B2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

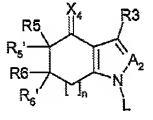
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9, and 24 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Fick et al. (WO 03/011396 A1, previously cited).

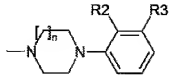
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

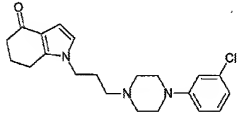
Fick et al. teach tetrahydroindolone and purine derivatives linked to arylpiperazines in pharmaceutical compositions containing a pharmaceutical excipient useful in treating anti-psychotic disorders (see abstract, pg. 1, paragraph 0002, and pg. 41, paragraphs 0129-0130). Fick et al. further teach that the compounds consists of two moieties, moiety A and B which a tetrahydroindolone comprises a moiety A linked through a linker L to a moiety B, where B is an arylpiperazinyl moiety (see abstract and pg. 2, paragraph 0005). Fick et al. teach that the A moiety is an e-10 atom bicyclic moiety in which five aromatic membered ring has 1 to 2 nitrogen atoms with the following formula I:



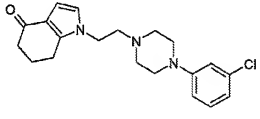
wherein formula I is bonded to a hydrocarbyl linker; A2 is C; R3 is hydrogen; X4 is O; R5 and R5' are hydrogen; R6 and R6' Are hydrogen; and n is 1 (see pgs. 4-5, paragraphs 0011-0013). The hydrocarbyl linker is preferably with the structure (CH2)m wherein m is an integer from 1 to 6 or wherein the preferred linker has m equal to 2, 3, or 4 (see pg. 12, paragraph 0045). As for the B moiety, it is an arylpiperazine or derivative having the structure of formula VII:



where R2 is H, alkyl, hydroxy, halo, alkoxy, cyano; R3 is H, alkyl, hydroxy, methoxy, halo, alkoxy, trifluoromethyl, nitro, amino, aminocarbonyl, aminosulfonyl; or where R2 and R3 can be taken together to form a 5 to 6 member aromatic or non-aromatic ring, which can contain 0 to 3 heteroatoms selected from the group of N, O, or S. and n=1 (see pg. 12, paragraphs 0047 and 0049). Particularly, Fick et al. teach various compounds such as Neo-363



and NEO-376



that render obvious applicant's invention (see pgs. 17-19, compounds 3 & 6).

Fick et al. do not specifically teach compounds wherein R6 is an alkyl group.

However, the Examiner contends that while Fick et al. do not teach R6 to be an alkyl group, Fick et al. do teach R6 to be a hydrogen atom. It is generally noted that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Lincoln, 126 U.S.P.Q. 477, 53 U.S. P.Q. 40 (C.C.P.A. 1942); In re Druey, 319 F.2d 237, 138 U.S.P.Q. 39 (C.C. P.A. 1963); In re Lohr, 317 F.2d 388, 137 U.S.P.Q. 548 (C.C.P.A. 1963); In re Hoehsema, 399 F.2d 269, 158 U.S.P.Q. 598 (C.C.P.A. 1968); In re Wood, 582 F.2d 638, 199 U.S. P.Q. 137 (C.C.P.A. 1978); In re Hoke, 560 F.2d 436, 195 U.S.P.Q. 148 (C.C.PA.A. 1977); Ex parte Fauque, 121 U.S.P.Q. 425 (P.O.B.A. 1954); Ex parte Henkel, 130 U.S.P.Q. 474, (P.O.B.A. 1960). Likewise, the Examiner maintains that substitution of an ethyl group for the hydrogen would have yielded similar properties as extension by one carbon chain is expected to behave similarly. In fact, the MPEP states that homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978). Given that applicant did not provide unexpected or unobvious results of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to substitute the "H" group to a "methyl" or an "ethyl" group. Moreover, the Examiner contends that such compounds are obvious variants of one another and are therefore expected to behave similarly given their similar structure.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute a methyl group or an ethyl group at the R6 position for the hydrogen since such compounds are obvious variants and structurally similar and thus expected to behave similarly. Thus, given the teachings of Fick et al., one of ordinary skill would have been motivated to formulate the compounds of Fick et al. with a methyl or an ethyl group at the R6 position of formula VII with the reasonable expectation of providing compounds that are highly bioavailable and useful in the treatment of psychotic disorders.

Objections

Claims 7-8, 19-20, and 22-23 are objected to because of the following informalities: Claims are dependent upon rejected claims. Appropriate correction is required.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1627

02/17/2010

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627